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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,906	12/19/2001	Kyoko Kojima	HITA.0135	8851

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/020,906

Applicant(s)
Kojima

Examiner
Arun Chakrabarti

Art Unit
1634



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 19, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 10/020,906.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☒ Other: Detailed Action

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DETAILED ACTION

Specification

1. Claim 11 is objected over the recitation of the word, "climed". It is not clear what is meant by the word in absence of a dictionary meaning. Proper correction is suggested by using the word, "claimed".

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-13 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 -13 are rejected over the recitation of the phrase, "**absorbing** the nucleic acids on an **adsorption** support" in claim 1. It is not clear if absorption is claimed or adsorption is claimed or both of them are claimed. It is also not clear how **absorption** is being carried out on an **adsorption** support. The claim is also confusing because line 4 recites, "**absorbing** the nucleic acids", whereas line 5 recites, "**adsorbed** with the nucleic acids". The metes and bounds of the claims are vague and indefinite. This rejection is based on the fact that "**absorption**" and "**adsorption**" are two completely different events. Copies of dictionary meanings are enclosed herewith.

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Claim 1 is also rejected because "support" on line 5 lacks antecedent basis if nucleic acids are absorbed on step 2. The word "nucleic acids salts" on line 2 also lacks antecedent basis.

Claims 1 -13 are rejected over the recitation of the phrase, "nucleic acids salts" in claim 1. It is not clear if nucleic acids and salts are claimed separately or salts made of nucleic acids are claimed or both of them are claimed. The metes and bounds of the claims are vague and indefinite.

Claim 18 is rejected over the recitation and repetition of the same phrase "aliphatic, aliphatic ester". It is not clear if a special kind of ester is claimed by the repetition of the phrase aliphatic or any aliphatic group of compound along with ester is claimed or both are claimed or it is a typo. The metes and bounds of the claim is vague and indefinite.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 5, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by

Crauthers et al. (U.S. Patent 5,153,319) (October 6, 1992). This rejection is based on the assumption that adsorption is carried out to purify the nucleic acid.

Crauthers et al teach a method for isolating and purifying nucleic acids, which comprises:

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a) providing a mixed solution containing the nucleic acids salts, and at least one organic solvent:

b) adsorbing the nucleic acids on a support;

c) washing the support adsorbed with the nucleic acids with a washing buffer;

d) desorbing the nucleic acids from the support with an elution buffer thereby recovering the nucleic acids, wherein the organic solvent includes at least one compound containing 2 to 10 carbon atoms selected from aliphatic ether tetrahydrofuran (Example 5, Column 16, line 43 to Column 17, line 37).

Crauthers et al inherently teach the method for isolating and purifying nucleic acids, further comprising:

providing a column with a bottom;

placing the support above the bottom;

causing the mixed solution to pass one-way through the support to the bottom by a sucking force (Example 5, Column 16, line 43 to Column 17, line 37).

6. Claims 14, 15, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamazaki et al (U.S. Patent 5,910,423) (June 8, 1999).

Yamazaki et al teach a reagent kit, which comprises a mixed solution containing salts, a washing buffer, and an elution buffer, wherein the organic solvent comprises aliphatic ether tetrahydrofuran, 1,4-dioxane and aliphatic ketone acetone and methyl ethyl ketone (Column 4, lines 30-49).

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Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) over Crauthers et al. (U.S. Patent 5,153,319) (October 6, 1992).

Crauthers et al teach the method of claims 1, 2, 5, and 11 as described above.

Crauthers et al do not teach the method wherein the concentration of the organic solvent in the mixed solution is 5% to 50% by volume and not more than 50% by volume.

However, it is *prima facie* obvious that selection of the specific concentration of the organic solvent represents routine optimization with regard to the isolation and purification of a desired length of a nucleic acid polymer and desired source of nucleic acid, which routine

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optimization parameters are explicitly recognized to an ordinary practitioner in the relevant art. As noted *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the specific concentration selection performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

9. Claims 3, 4, and 8-10 are rejected under 35 U.S.C. 103(a) over Crauthers et al. (U.S. Patent 5,153,319) (October 6, 1992) in view of Baldwin et al. (U.S. Patent 6,368,400 B1) (April 9, 2002).

Crauthers et al teach the method of claims 1, 2, 5, and 11 as described above.

Crauthers et al do not teach the method wherein the organic solvent comprises ethyl lactate, acetone, a surfactant and a defoaming agent .

Baldwin et al. teach the method wherein the organic solvent comprises ethyl lactate, acetone, a surfactant , and a defoaming agent (Column 6, lines 6-27).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method wherein the organic solvent comprises ethyl lactate, acetone, and a surfactant of Baldwin et al with the methods of isolating

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nucleic acids of Crauthers et al., since Baldwin et al state, "Dilutant solvents with high boiling points such as ethyl lactate and propylene glycol propyl ether have been found to be beneficial (Column 6, lines 12-14)". An ordinary artisan would have been motivated by these express statements of Gelfand et al to substitute and combine the method wherein the organic solvent comprises ethyl lactate, acetone, and a surfactant of Baldwin et al with the methods of isolating nucleic acids of Crauthers et al., in order to achieve the express advantages of dilutant solvents with high boiling points such as ethyl lactate and propylene glycol propyl ether which have been found to be beneficial.

Crauthers et al. in view of Baldwin et al do not teach the method wherein the concentration of the surfactant in the mixed solution is 5% to 50% by volume and not more than 50% by volume and a defoaming agent concentration is at 0.2% to 2.5% by volume..

However, it is *prima facie* obvious that selection of the specific concentrations of the surfactant and defoaming agent represent routine optimization with regard to the isolation and purification of a desired length of a nucleic acid polymer and desired source of nucleic acid, which routine optimization parameters are explicitly recognized to an ordinary practitioner in the relevant art. As noted *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the

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specific concentration selection performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

10. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) over Crauthers et al. (U.S. Patent 5,153,319) (October 6, 1992) in view of Dale et al. (U.S. Patent 6,211,349 B1) (April 3, 2001).

Crauthers et al teach the method of claims 1, 2, 5, and 11 as described above.

Crauthers et al do not teach the method wherein the mixed solution also passes through the support the other way by an opposite sucking force a number of times to enhance adsorption efficiency.

Dale et al. teach the method wherein the mixed solution also passes through the support the other way by an opposite sucking force a number of times to enhance adsorption efficiency by reverse phase chromatography (Column 10, lines 40-60 and Example 2).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method wherein the mixed solution also passes through the support the other way by an opposite sucking force a number of times to enhance adsorption efficiency of Dale et al with the methods of isolating nucleic acids of Crauthers et al., since Dale et al state, "Nucleic acids of the present invention can be purified by chromatography on commercially available reverse phase media (Column 10, lines 42-44)". An ordinary artisan would have been motivated by these express statements of Dale et al to substitute and combine the method wherein the mixed solution also passes through the support the other

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way by an opposite sucking force a number of times to enhance adsorption efficiency of Dale et al with the methods of isolating nucleic acids of Crauthers et al., in order to achieve the express advantages, as noted by Dale et al., of nucleic acids purification by chromatography on commercially available reverse phase media.

11. Claim 16 is rejected under 35 U.S.C. 103(a) over Crauthers et al. (U.S. Patent 5,153,319) (October 6, 1992) in view of Baldwin et al. (U.S. Patent 6,368,400 B1) (April 9, 2002) further in view of Stratagene Catalog ((1988) page 39).

Crauthers et al. in view of Baldwin et al. expressly teaches the claims 3, 4, and 8-10 as described above with ethyl lactate as a solvent.

Crauthers et al. in view of Baldwin et al do not provide a motivation to make kits with ethyl lactate as a solvent.

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method and reagents of Crauthers et al. in view of Baldwin et al into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments.

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When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746-4979. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

March 12, 2003

Arun K. Chakrabarti
ARUN K. CHAKRABARTI
PATENT EXAMINER